



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,730	04/24/2001	Se-Jin Lee	JHU1470-3	6537

7590 07/09/2004

Lisa A. Haile  
GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive Suite 1100  
San Diego, CA 92121-2133

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/841,730

Applicant(s)

LEE ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-3,5,13,14,20 and 40-45.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

*Joe Woitach*  
AUG 32

Continuation of 5. does NOT place the application in condition for allowance because: Applicants summarize the basis of the invention and argue that a dominant negative form of Act RIIb correlates with GDF-8 mutations that result in the inhibited expression of myostatin (page 6). Further, it is argued that this activity based on the homology of known Act RII would extend to all mammals (page 7). Citing several new references Applicants argue that one of skill in the art could have made the appropriate Act RII constructs and used them in methods known in the art to generate the transgenic animals encompassed by the claims. As indicated during the phone interview and in the basis of the rejection Examiner would agree that the truncated Act RIIb when expressed in the mouse would result in increased muscle mass. Further, based on the evidence provided in the instant amendment, Examiner would agree that there is sufficient homolog among mammalian sequences that one of skill in the art would conclude that there is a function/structure relationship among the encoded proteins. However, it is noted that the claims have not been amended and Applicants arguments fail to address the basis of the rejection regarding the breadth of the types of sequences that can be expressed, and the amount of expression of transgene to result in any affect. Examiner would agree that the affect of Act RII and GDF-8 mutants is at the level of myostatin and that a dominant negative form of Act RII will likely result in affecting myostatin, however the claims clearly encompass sequences that are not dominant negative sequences. Moreover, even if the claims were amended to indicate that the sequence expressed was that of a dominant protien, there is a still a requirement for adequate expression of the protein to adequately compete with the normal endogenous copy to have any observable phenotypic affect in the resulting transgenic mammal. Without clear guidance to the requirements of the promoter or amounts of protein that need to be expressed, the skilled artisan would be required to do empiracal experimentation to supplement the shortcomings in the teachings of the instant specification. Applicants arguments have been fully considered and found persusive in part, however the rejectio is maintained because of the breadth of the claims and the evidence of record requiring empiracal experimatnation in the unpredictable a of transgene expression.